

A3 of said blood, whereby centrifugal forces applied to said assembly enable elongation of said bellows and movement of said separator assembly in said tube to a location between said formed and liquid phases of said blood.

A4 12. (amended) The assembly of claim 10, wherein said ballast is substantially tubular and is securely engaged around portions of bellows adjacent the lower end of said bellows.

A5 16. (new) The assembly of claim 1, wherein the closed bottom comprises an opening having a closure sealingly engaged therein, the closure comprising a needle-pierceable elastomer material.

Remarks

Introduction

Claims 1-3, 5-10, and 12-16 are pending.

Applicants have cancelled claims 4 and 11, which, as the Examiner pointed out, were redundant, and the dependency of claim 12 has been amended accordingly. Claims 1 and 10 have been amended, as discussed further below. New claim 16 has been added, and reflects an embodiment shown in Fig. 16 and discussed at page 17, lines 23-27 of the application..

Applicants have also amended the application to claim priority of an earlier application, and indicate that the present application is a continuation-in-part of that earlier application. Upon analyzing the present application, it was realized that such a priority claim was appropriate.

Claim Objection

The Examiner objected to claims 5 and 12, as being of improper form. Claims 4 and 5 were redundant, and applicants have cancelled claim 4. Similarly, claims 11 and 12 were redundant, and applicants have cancelled claim 11.

Rejections Under 35 U.S.C. § 112

The Examiner rejected claims 1-15 under § 112, second paragraph, as being indefinite. Specifically, the Examiner points to (1) recitations of the density of the ballast and float relative to the liquid and formed phases of the sample, and (2) some language that describes the density of the float. In view of the amendments made herein, the rejection is respectfully traversed.

Regarding matter (2), Applicants have amended claims 1 and 10 to correct some errors with respect to the density of the float – in one case a redundancy has been deleted, and in the other a correction to state that the density of the float is less than the density of the liquid phase, as discussed, e.g., in the Summary of the present application.

Regarding matter (1), § 112, second paragraph, requires only that the scope of the claimed invention be clear to one skilled in the art. One skilled in the art would have no trouble understanding that the density of the float or the ballast has a certain relationship to the density of a particular phase of a sample that will be collected. Applicants note, for example, the numerous patents in this technology that contain claims having this type of language.

For these reasons, withdrawal of the rejection is respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1-15 were provisionally rejected under § 102(e) as being anticipated by copending, and coassigned, application serial number 09/454,988 (“the ‘988 application”). As noted by the Examiner, there is overlapping description between the ‘988 application and the present application.

As discussed above, and in agreement with the Examiner’s comments, applicants have amended the present application to state that it is a continuation-in-part of the ‘988 application. Applicants believe this addresses the § 102(e) rejection.

Double Patenting Rejection

Claims 1-15 were rejected under the doctrine of obviousness-type double patenting, as being unpatentable over claims of the ‘988 application, alone or in view of U.S. Patent No. 6,085,944 to Lang et al. or U.S. Patent No. 4,083,788 to Ferrara.

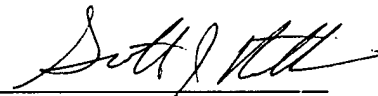
Applicants have filed herewith a terminal disclaimer, with respect to the '988 application. Applicants believe the terminal disclaimer fully addresses this rejection.

In view of the amendments and remarks above, applicants respectfully request reconsideration of the application, and allowance of all claims.

If there are any additional fees related to this Amendment, such fees should be charged to Deposit Account No. 02-1666.

Respectfully submitted,

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Date: Jul 3, 2002

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Marked-Up Version of the Description:

At page 1, line 12, insert the following paragraph:

This application a continuation-in-part of, and claims priority from, U.S. patent application serial number 09/454,988 filed December 3, 1999, which claims priority from U.S. provisional patent application serial number 60/110,934 filed December 5, 1998.

Marked-up Version of the Claims:

1. (amended) An assembly for enabling separation of a fluid sample into a formed phase with a relatively high density and a liquid phase with a relatively low density, said assembly comprising:

a tube having a closed bottom, an open top and a cylindrical sidewall extending therebetween;

a closure sealingly engaged with said open top of said tube; and

a separator comprising a deformable bellows having an upper end and a lower end, portions of said bellows between said upper and lower ends having an unbiased shape for sealing engagement with said cylindrical sidewall of said tube, a ballast securely mounted in proximity to said lower end of said bellows, said ballast being dimensioned to be spaced inwardly from said cylindrical sidewall of said tube and having a density greater than said density of said liquid phase of said fluid sample, and a float engageable with portions of said bellows in proximity to said upper end of said bellows, said float having a density less than said density of said formed liquid phase of said fluid sample ~~and less than said density of said formed phase of said fluid sample~~, whereby centrifugal forces applied to said assembly enable elongation of said bellows and movement of said separator in said tube to a location between said formed and liquid phases of said fluid sample.

10. (amended) A separator for use with a blood collection tube to enable separation of blood into a formed phase with a relatively high density and a liquid phase with a relatively low density, said separator assembly comprising:

a deformable bellows having an upper end and a lower end, portions of said bellows between said upper and lower ends having an unbiased shape for sealing engagement within said tube;

a ballast securely mounted to said bellows in proximity to said lower end of said bellows, said ballast having cross-sectional dimensions smaller than said tube for free movement of said ballast in said tube, said ballast having a density greater than said density of said liquid phase of said blood; and

a float engageable with portions of said bellows in proximity to said upper end of said bellows, said float having a density less than said density of said liquid phase of said blood ~~and less than said density of said formed phase of said blood~~, whereby centrifugal forces applied to said assembly enable elongation of said bellows and movement of said separator assembly in said tube to a location between said formed and liquid phases of said blood.

12. (amended) The assembly of claim ~~11~~ 10, wherein said ballast is substantially tubular and is securely engaged around portions of bellows adjacent the lower end of said bellows.